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| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
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|--------------------|-------------|-----------------------|------------------|

08/460,186 06/02/95 VON BORSTEL

R 1331-138

EXAMINER

HM12/0913

NIXON AND VANDERHYE
1100 NORTH GLEBE ROAD
8TH FLOOR
ARLINGTON VA 22201

ART UNIT 2, 3 PAPER NUMBER

15

1623

DATE MAILED:

09/13/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 7-16-99
- ☒ This action is **FINAL**
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-25 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-25 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

08/460,186
PTOL-326 (Rev. 9/96)

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Detailed Action

Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a). Applicant's **SECOND** submission after final filed on 5-26-98 has been entered.

Claims 1-25 are pending in the case.

All 35 USC statutes not cited in this Office action can be found cited in full in a previous Office action.

Provisional Obviousness-Type Double Patenting

The provisional obviousness-type double patenting rejection set forth on pages 2-3 of the Office action mailed 9-3-96 continues to be held in abeyance until allowable subjected matter is indicated.

35 USC 103 Rejections

Claims 1-15, 18-19, and 22-25 stand rejected under 35 USC 103 as being unpatentable over Martin et al. and Sommadossi et al. in view of Von Borstel et al. (WO 89/03837) for the reasons already set forth on pages 2-5 of the Office action mailed 9-3-96. Applicant's arguments have been fully considered but are not deemed persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections

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are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The applicant also argues against this obviousness rejection by pointing out that TAU, when coadministered with 5-FU, has unexpectedly consistently shown the ability to achieve complete regression of tumors in 60-80% of the cases. The applicant further indicates that TAU has reduced the GI damage due to large dose of 5-FU. These unexpected results may well be sufficient to overcome the instant art rejections. However, this information is not in the specification and should, therefore, be presented in affidavit form.

Claims 16-17 and 20-21 stand rejected under 35 USC 103 as being unpatentable over Bhalla et al. in view of Von Borstel et al. and Hanze et al. for the reasons already of record on pages 5-6 of the Office action mailed 9-3-96. The applicant's instant arguments against this obviousness rejection have already been responded to on page 4 of the Office action mailed 5-27-97.

35 USC 112, First Paragraph Rejection

Claims 1, 3-13, and 24-25 stand rejected under 35 USC 112, first paragraph, for the reasons already of record on page 4 of the Office action mailed

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The applicant argues against this scope rejection on the grounds that limiting the claims to acylated derivatives of uridine, cytidine, 2'-deoxyuridine, or 2'-deoxycytidine would "enable third party infringers to take advantage of the invention while readily avoiding infringement". This argument has been fully considered but is not deemed persuasive. The examiner has pointed out that the claims encompassing "any acylated non-methylated pyrimidine analog" embrace many compounds which cannot possibly reduce the toxicity of chemotherapeutic agents, i.e. N4-cyclopropylcytidine, 4-thiouridine, 4-selenouridine, etc. Therefore, the person or skill in the art would have sound reason to believe that non-methylated pyrimidine nucleosides outside of uridine, 2'-deoxyuridine, cytidine, and 2'-deoxycytidine would actually increase the toxicity of chemotherapeutic agents.

No claim is allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.129(a) and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.129(a). Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the submission under 37 CFR 1.129(a). See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kunz, whose telephone number is (703) 308-4623. The examiner can normally be reached on Tuesday through Friday from 6:30 AM to 4:00 PM. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, a supervisory patent examiner can be reached: Cecilia Tsang at (703) 308-4311 or Gary Jones at (703) 308-1152. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.


GARY L. KUNZ
PRIMARY EXAMINER
GROUP 1200